

**TAB 55**



INTEROFFICE MEMORANDUM

TO: R. FROMUTH  
FROM: BRUCE BANKS  
SUBJECT: CONTRACT MANUFACTURING AND DISTRIBUTION AGREEMENT  
DATE: 9/19/2005  
CC:

A copy of the fully executed Agreement is enclosed for your files.

8/31/05

## CONTRACT MANUFACTURING AND DISTRIBUTION AGREEMENT

This Agreement is entered into this 16<sup>th</sup> day of Septemeber 2005, by and between Boehringer Ingelheim Pharmaceuticals, Inc., 900 Ridgebury Road, Ridgefield, CT 06877 (hereinafter referred to as "BIP") BIRI and Boehringer Ingelheim Roxane, Inc., 1809 Wilson Road, Columbus, Ohio 43228, (hereinafter referred to as "BIRI").

WHEREAS, BIP is the owner of, or has acquired rights to various Drug Products; and

WHEREAS, BIP is desirous of having BIRI Manufacture (as hereinafter defined) for it Drug Products in accordance with BIP's Specifications (as hereinafter defined); and

WHEREAS, BIRI possesses valuable production facilities, know-how and employs personnel having skills relative to the preparation of Drug Products and is willing to Manufacture and sell such Drug Products to BIP in finished package form in labeled put-ups.

NOW THEREFORE, in consideration of the premises and the undertakings of the parties hereinafter set forth the parties agree as follows:

### 1. DEFINITIONS

1.1 "Agency" or "Agencies" shall mean any governmental regulatory authority involved in granting approvals for the manufacturing or sale of the Drug Products, including without limitation, the U.S. Food and Drug Administration (FDA), Drug Enforcement Agency (DEA), Canadian Health Protective Branch (CHPB), European Agency for Evaluation of Medicinal Drug Products (EMEA) and any other equivalent authority within the European Union).

1.2 "Applicable Laws" shall mean all material foreign and United States federal, state and local laws, statutes, rules and regulations, applicable to the manufacture and distribution of the Drug Products, including, without limitation, the applicable regulations and guidelines

8/31/05

of the FDA, DEA, CHPB and EMEA. In the event of any conflict between the foregoing sources of authority, the United States federal law and regulation shall be given priority.

1.3 "Batch" shall mean the quantity of each respective Drug Product that is intended to have uniform character and quality with the Specifications and is Manufactured by BIRI during a standard production run, the size of which is mutually agreed upon.

1.4 "cGMP" shall mean all laws and regulations relating to the manufacturing of the Drug Product, including, but not limited to, the Current Good Manufacturing Practices specified in the U.S. Code of Federal Regulations (21 CFR Articles 210, 211 et seq.) and the provisions of Commission Directive 2003/04/EC as well as any other applicable laws, guidelines and/or regulations included under this Agreement pursuant to Section 7.4, in each case as may be amended from time to time.

1.5 "Drug Product" shall mean those pharmaceutical compound(s) either individually or in the aggregate designated in Attachment A-1, which are packaged in final finished package form, as well as such other pharmaceutical preparations subsequently identified by mutual written consent of the parties. Drug Product for which BIRI only provides purchasing and/or warehousing and/or distribution shall be identified in Attachment A-2.

1.6 "Manufacture" or "Manufacturing" or "Manufactured" shall mean, as applicable any or all of the production, packaging, labeling, warehousing, quality control testing, (including in-process, release and stability testing) and release of the Drug Product meeting the Specifications for the Drug Product.

1.7 "Marketing Authorization" shall mean any license of approval of any Agency necessary for the marketing and sale of a Drug Product.

1.8 "Permits" shall mean all permits, licenses, registrations, orders, authorizations or approvals of any federal, state or local governmental body or Agency.

1.9 "Product Distribution Services" shall mean BIRI's distribution of Drug Products to such parties as designated by BIRI.

8/31/05

1.10 "Product Manager" shall mean the appropriate person in BIPI's Marketing Department who is responsible for a particular Drug Product.

1.11 "Recall" shall mean any voluntary or involuntary removal, stop sale, governmental action or directive, which results in the removal or correction of a Drug Product that is on the market.

1.12 "Specification" shall mean any and all specifications for the Manufacturing of a Drug Product, including but not limited to the specifications as set forth in its Marketing Authorization.

1.13 "Term" shall mean the Initial Term and any Renewal Term(s) as hereinafter defined.

1.14 "Trademark" shall mean those trademarks and the trade-dress used by BIPI in identifying a Drug Product.

## **2. QUANTITY AND RIGHT OF FIRST OPPORTUNITY**

2.1 BIRI shall sell to BIPI and BIPI agrees to purchase from time to time from BIRI, subject to the terms and conditions hereinafter set forth, quantities of the Drug Product(s) during the Term.

## **3. TERM OF AGREEMENT**

3.1 This Agreement shall extend from the date first set forth above and shall continue for a ten (10) year, (the "Initial Term). Thereafter, the Agreement shall be automatically renewed for successive periods of three (3) years, each a Renewal Term[s], unless or until written notice of termination is given by either party to the other on not less than three (3) years written notice prior to the end of the Initial Term or any Renewal Term(s), or unless sooner terminated or modified pursuant to one of the remaining provisions of this Agreement.

8/31/05

3.2 This Agreement may be terminated by written notice by either party in the event that the other has defaulted in any material manner and shall have failed to remedy such default within one hundred eighty (180) days after notice thereof from one party to the other party.

3.3 Upon the expiry, termination or cancellation of this Agreement for any reason, by either Party, BIPI shall purchase from BIRI all remaining Drug Product, work-in-process, ingredients, and components which are used to manufacture such Drug Product, which BIRI would not have manufactured or purchased except for its Manufacture of the such Drug Product for BIPI, at the price(s) then effect. At BIPI's option, the foregoing inventories shall be destroyed or shipped to BIPI or its designee at BIPI's expense.

3.4 This Agreement may be terminated on a Drug Product by Drug Product basis on a mutually agreed timeframe without terminating the entire Agreement.

3.5 Termination of this Agreement shall not relieve either party from any liabilities or obligations which may have accrued prior to the date of termination, including the obligation to pay for Drug Product delivered to BIPI or the mutual obligations of confidentiality and indemnity.

#### 4. PERFORMANCE

4.1 BIPI and BIRI shall share know-how and technical information and associated services to enable BIPI to file and/or modify its Marketing Authorization and to permit BIRI to Manufacture Drug Product, in conformity with BIPI's Marketing Authorization and the Specifications.

4.2 Either of the parties shall have the right to request changes to the Specifications. No change in the Specifications with respect to the packaging, labeling, Trademark, physical characteristics or components shall be made or implemented by BIRI, until the parties have agreed in writing to such change and the date of its implementation. Changes to any of the other Specifications, shall be in writing and communicated by BIRI to BIPI, indicating any impact on the cost and/or impact on productivity.

4.3 BIRI shall prepare for shipment and ship all such Drug Products in accordance with all the quality control measures established by BIRI and set forth in the Specifications. During such Manufacturing, preparing for shipment and shipping, BIRI shall perform quality assurance

8/31/05

testing of its manufacturing process and the Drug Products as specified in the Specifications. Appropriate documentation of final quality assurance release of Drug Product to inventory and certificates of analysis shall be provided to BIPI by BIRI upon request.

4.4 The Drug Product shall be labeled, prepared and packed for shipment in accordance with BIRI's customary practice, and the Specifications. BIPI shall specify the trade dress and trademarks which will appear on the label, and package inserts identifying the Drug Product. BIRI will prepare camera ready art, product mock-ups, electronic labeling, for all the Drug Products, except as otherwise agreed. In addition, BIRI shall provide specimens of the Drug Product, as requested, to be used for graphic purposes.

4.5 Lot numbers shall be affixed, imprinted or otherwise included on the containers for the Drug Product in accordance with BIRI's customary practice and the Specifications.

4.6 Any Drug Product found not to have been Manufactured in accordance with Specifications shall be replaced by Drug Product conforming to the Specifications at no cost to BIPI, at the earliest practical date. If however, the reason for the lack of conformance to Specifications was the result of any component, excipient, active pharmaceutical ingredient, the Specifications, the Marketing Authorization, or any labeling given by BIPI to BIRI to Manufacture of the Drug Product, BIPI shall bear the cost for the replacement of such drug product.

4.7 Inventories of Drug Product, ingredients, packaging and labeling components, in-process work and any finished goods which cannot be used by BIRI as the result of a change in the Specifications shall be identified by BIRI's Director of Quality Control notifying the appropriate BIPI Product Manager and charged to BIPI at BIRI's cost, provided BIRI has not maintained inventories which are inconsistent with BIPI's planned purchases as set forth in Article 6.

4.8 BIRI shall promptly notify BIPI of any problems or unusual production situations which have the potential to adversely affect the Manufacture of the Drug Product, or its timely delivery to the parties designated by BIPI customers. The Parties shall keep each other informed of all developments during any such period of inability to Manufacture and shall cooperate so that BIPI will be able to secure forecasted quantities of Drug Product with the least amount of disruption to supply.

8/31/05

4.9 Validation Batches which are Manufactured to secure a Marketing Authorization and which are Manufactured in accordance with the Specifications and Marketing Authorization may be sold by BIRI to BIPI as Drug Product to BIPI under this Agreement.

4.10 BIRI shall be entitled to perform any of its obligations and duties hereunder through a third party designee, but shall provide prior notice to BIPI for approval, such approval to not be unreasonably withheld. It is understood that such third party designee shall be bound to perform under the terms and conditions of this Agreement and BIRI shall be responsible for such designees performance.

## 5. FORECAST AND ORDER PROCEDURE

5.1 BIPI agrees to purchase the Drug Product in production Batch quantities or multiples thereof.

5.2 On or before the fifteenth day of each calendar month during the Term, BIPI shall submit to BIRI a rolling forecast of its Drug Product requirements for the next eighteen months (18 months). Each Forecast shall be prepared in good faith and shall represent the best estimate of BIPI as to the quantity of the Drug Product BIPI expects to purchase from BIRI during the period covered by such Forecast. The Drug Product requirements set forth for the first two (2) full months of each Forecast, shall be binding, although BIRI will endeavor to meet any request by BIPI for quantities of Drug Product which are greater than set forth in such rolling two (2) month binding forecast period. The Drug Product requirements set forth for the remaining sixteen months (16 months) of each Forecast shall be non-binding, although, BIPI shall attempt to level load its requests as much as possible and alert BIRI as soon as reasonably possible of any significant changes occurring in the Forecast.

5.3 BIRI shall supply, and BIPI shall purchase Drug Products pursuant to the Forecast as set forth above.

5.4 Title to only that Batch quantity of Drug Product manufactured pursuant to the binding forecast shall pass to BIPI upon release of such quantity of Drug Product by BIRI's Quality Assurance Department. Risk of Loss for such quantity of Drug Product shall pass to BIPI at the time title passes to it.

8/31/05

5.5 In addition to the production forecasting obligations set forth in Paragraph 5.2, upon the execution of this Agreement and thenceforth during the Term of this Agreement the Parties shall meet annually and BIPI shall provide, BIRI with a non-binding projection of anticipated future demand of each Drug Product for the sole purpose of permitting BIRI to plan based upon the Management Enterprise Planning Cycle. During such meeting, the Parties shall meet to review and revise, as may be necessary, Attachments A-1 and A-2.

## 6. DISTRIBUTION OF PRODUCTS

6.1 BIRI shall provide distribution services pursuant to BIPI's reasonable request. Distribution Services shall consist of (i) storage of the Drug Products in compliance with all Applicable Laws, (ii) receipt, checking, preparation and maintenance of Form 222 or other order forms, export permits and other records required by any Agencies for distribution of the Products; and (iii) packing and preparing orders for shipment of the Drug Products to such parties designated by BIPI and, (as identified on BIPI's customer lists which will be updated and provided to BIRI). Distribution Services shall not include, and BIPI shall be solely responsible for freight charges, which will be billed to BIPI directly. Upon receipt of a valid order from BIPI or its designee, BIRI shall pack and prepare the order for carrier pick-up within forty-eight (48) hours, unless otherwise specified by BIPI and agreed to by BIRI.

6.2 BIPI shall be responsible for any losses or damage in shipment and for invoicing and collecting payments from its customers. In the event of losses or damages in shipment of which it becomes aware, BIRI shall notify BIPI promptly. BIRI shall be entitled to perform any or all of its obligations and duties hereunder through a third party designee without providing notice to or receiving consent from BIPI.

## 7. PAYMENTS

7.1 BIRI agrees to sell and BIPI agrees to purchase the Drug Product at the prices set forth in BIRI's Enterprise Resource Plan. Payment terms are net 30 days.

8/31/05

7.2 The prices for the Drug Products on Schedule A-1 to be marketed and sold as of the date first set forth above shall remain fixed until the end of each calendar year. Thereafter, the parties shall set the prices for the Drug Products, not less than once per year, based on BIRI's costs plus ten percent (10%).

7.3 BIPI agrees to pay a monthly distribution fee equal to one hundred and two percent (102%) of BIRI's cost of providing Drug Product Distribution Services for products distributed under Attachment A-1 and A-2, based upon BIRI's warehousing costs and rent (the Distribution Fee). Payment terms are net thirty (30) days.

7.4 Customs duties and related fees shall be the responsibility of the importer of record.

## **8. ADVERSE DRUG AND DRUG PRODUCTCOMPLAINT REPORTS**

8.1 BIPI shall be responsible for reporting to the FDA, if required, any adverse drug experiences associated with the Drug Product, provided that BIRI promptly notify BIPI of any adverse drug experience report(s) that it receives.

8.2 If BIRI receives any reports of adverse drug experience associated with a Drug Product, or other complaints about a Drug Product, BIRI shall provide BIPI with a copy of such report(s) within five (5) business days of the receipt of same, or sooner as required by the FDA.

## **9. TRADEMARKS**

9.1 BIRI recognizes and agrees that the trademark selected by BIPI for use in connection with the Drug Product and the trade-dress, labels, or labeling or designs used in connection with the

8/31/05

such Drug Product are the property of BIPI and that it will have no rights in or to the said Trademarks

#### **10. CONFIDENTIALITY**

10.1 Each party agrees that all data and information received by it pursuant to this Agreement shall be retained in confidence. Each party shall bind the recipients of such information to the confidentiality terms contained herein. This commitment shall not apply if the information is or becomes public knowledge without the fault of the recipient party; or where the information is properly provided to a party by an independent third party; or where a party can show by written record that the information was already in its possession at the time of receipt from the other party; or where the information is required or subpoenaed by any governmental agency, body or Court who shall be informed of the confidential nature of such information. The obligations under this paragraph shall survive the TERM.

#### **11. REPRESENTATIONS AND WARRANTIES**

11.1 Each Party represents and warrants to the other Party that:

- a) it has the full corporate right, power and authority to execute, deliver and perform this Agreement and to consummate the transactions contemplated hereby, and the execution, delivery and performance of this Agreement and the consummation of the transactions hereby have been duly authorized by all necessary corporate action on the part of such party;
- b) it's execution, delivery and performance of this Agreement shall not constitute a breach or default under any contract or agreement to which such party is a party or by which it is bound or otherwise violate the rights of any third party; and
- c) except as expressly set forth elsewhere herein, no further consent, approval or authorization of or from any governmental entity or any other third party, whether prescribed by law, regulation, contract or agreement, is required for such party's execution, delivery and performance of this Agreement or consummation of the transactions contemplated hereby.

8/31/05

d) neither party nor any member of its staff has been disqualified or debarred by FDA, nor has any member of its staff been charged with or convicted under federal or state law for conduct relating to the development or approval, or otherwise relating to the regulation of any drug product under the Generic Drug Enforcement Act of 1992 or any other relevant statute, law or regulation.

11.2 BIRI represents and warrants that the Drug Product, packaging components and labeling components shall conform to the Specifications and that the Drug Product shall be Manufactured in accordance with the Current Good Manufacturing Practice Regulations of the U.S. Food and Drug Administration, the Specifications and the Drug Products Marketing Authorization. BIRI warrants that the Drug Product shall not be a product which is adulterated or misbranded within the meaning of Section 505 of the Federal Food, Drug and Cosmetic Act, as amended, and the regulations issued thereunder or within the meaning of any state or local law, the adulteration and misbranding provisions of which are similar to the Federal Act or is a product which may not, under the provisions of any law or regulations, be introduced into interstate commerce. Excluded from the above representations and warranties are any failures of the Drug Product due to defects in the Specifications, the Drug Products Marketing Authorization, labeling or other components, excipients or active pharmaceutical ingredients provided by BIPI.

11.3 BIPI represents and warrants that it has no knowledge of any third party patent or trademark rights that would be infringed by BIRI's activities under this Agreement.

11.4 BIPI warrants that all label copy, artwork and all information approved by BIPI for use by BIRI shall not be false or misleading in any particular and shall be in compliance with applicable FDA regulations.

## 12 COMPLIANCE WITH LAWS, RECORD KEEPING, INSPECTIONS

12.1 BIRI and BIPI each have obtained and shall maintain all Permits, the absence of which would have a material adverse effect on that Party's ability to perform its obligations hereunder.

8/31/05

12.2 BIRI shall, with respect to any particular Batch of the Drug Product produced by it hereunder, for a period of five (5) years after the expiry of the expiration date of any such Batch, or for a longer period if required by law, keep documentation of the Drug Product including, without limitation, all such records which are required under Applicable Laws.

12.3 Inspections:

- a) Personnel from BIPI shall, upon reasonable advance notice to BIRI, but no more than twice each year, except as otherwise mutually agreed for good cause, have access during business hours to BIRI's premises where the Manufacture and distribution services are performed in order to observe and inspect the production, quality control and testing, equipment, storage and distribution facilities, personnel, and processes for, and the records of production, quality assurance, and other data or information related to, the Drug Products.
- b. BIRI and BIPI shall notify each other of any Agency inspection, investigation or other inquiry, or any third party action or inquiry, which may materially affect its ability to perform its obligations hereunder or the sale of the Products. BIRI and BIPI shall cooperate with each other in the context of any such inspection, investigation, action or other inquiry including, but not limited to, allowing upon request a representative of the other to be present during the applicable portions of any such inspection, investigation or other inquiry.

### 13. INDEMNITY/INSURANCE/RECALLS

13.1 BIPI shall defend, indemnify, protect, and save BIRI harmless from all claims, demands, suits, or proceedings for damages, costs (including reasonable attorney's fees), expenses and losses which arise (1) from any claim or charge by a third party for trademark or patent infringement, or unfair competition arising out of or in connection with the promotion, marketing, distribution or sale of the Drug Product by BIPI or of the use and manufacture of the Drug Product in conformity with the Specifications or (2) as the result of any breach of this Agreement by BIPI or (3) out of any claim for product liability arising from the use of the Drug Product; provided, however that BIRI will not be indemnified for any claims arising solely as the result of the Manufacture of the Drug Product which fails to conform to the Specifications or is in violation of the warranties set forth in Article 11.

8/31/05

13.2 BIRI shall defend, indemnify, protect, and save BIPI harmless from all claims, demands, suits or proceedings for damages and costs (including reasonable attorney's fees), expenses and losses which arise solely as the result of BIRI's failure to provide the Drug Product in conformity with the Specifications or in violation of the warranties set forth in Article 11.

13.3 The Party claiming indemnification shall, immediately upon receipt of notice of any such claim or suit, notify the other Party, fully cooperate with the other Party in defense of the claim or suit, or permit the other Party's attorney(s) to handle and control such claims or suits, except that the Party claiming indemnification shall be entitled to select counsel, participate therein and assume the defense thereof at its own expense, but in any event, shall keep such other Party informed of the progress of any such claims or suits including notification of final disposition.

13.4 Effective throughout the Term and thereafter, for a period of not less than four (4) years, the parties shall each carry and maintain in full force and effect insurance, insuring themselves for comprehensive general liability, including product liability.

13.5 Any expense incurred by BIRI from an injunction, recall, stop sale or governmental action or directive, shall be the responsibility of BIPI provided such actions, recall and/or stop sale does not arise from a breach of the Agreement by BIRI .

13.6 BIRI shall reimburse BIPI for all of its reasonable direct out-of-pocket costs and expenses, incurred in respect to any Recalls relating to the Drug Products deemed to be necessary by BIPI in BIPI's commercially reasonable judgment, to the extent that such Recall results from or arises out of any breach of any representation or warranty contained in this Agreement by BIRI. BIPI shall reasonably consult with BIRI and take into consideration BIRI's recommendations regarding such Recalls. Such out-of-pocket expenses shall be reimbursed by BIRI by the issuance of a credit, which shall only be applied against future purchases of Drug Product.

#### 14. GENERAL TERMS

14.1 This Agreement shall be governed and construed in accordance with the laws of the State of Ohio and any and all disputes arising under or concerning this Agreement shall be before the Courts of the State of Ohio. Notwithstanding the foregoing, the parties will use their best efforts to resolve any disputes that may arise.

8/31/05

14.2 Any notice, required or permitted to be given under this Agreement, shall be in writing, postpaid, by express, registered or certified mail or facsimile, addressed to the party to be notified at its address stated below:

If to BIRI:

Robert Fromuth  
Boehringer Ingelheim Roxane, Inc.  
1809 Wilson Road  
Columbus, Ohio 43228  
(614) 276-8508

If to BIPI:

Paul Fonteyne  
Boehringer Ingelheim Pharmaceuticals, Inc.  
900 Ridgebury Road  
Ridgefield, CT 06877  
(203) 798-9988  
cc: General Counsel

14.3 No liability shall result from delay in performance in whole or in part if performance as agreed has been made impracticable by compliance in good faith with any applicable foreign or domestic governmental regulations or order whether or not it later proves to be invalid, or by the occurrence of a contingency the non-occurrence of which was a basic assumption on which this Agreement was made, including, but not limited to, acts of God, fire, flood, accident, riot, war, sabotage, strike, labor trouble, shortage, or embargo.. If any such circumstances affect only a part of BIRI's capacity to perform, BIRI shall have the right to allocate production and deliveries among all of its customers and its own requirements. Quantities affected by this paragraph may, at the option of either party, be eliminated from the Agreement without liability, but the Agreement shall remain otherwise unaffected.

14.4 The failure of either party to insist on strict performance of any provision or to take advantage of any right hereunder shall not be construed as a waiver or any subsequent performance of such provision or right.

14.5 The headings and captions contained herein are for reference only and shall not constitute a substantive part of this Agreement.

14.6 The parties are and will remain at all times independent contractors, and no agency or employment relationship exists between them.

14.7 This Agreement may not be assigned by either party without the written consent of the other (which consent shall not be unreasonably withheld) except to an affiliate of either Party or in the

8/31/05

case of sale or transfer of all or substantially all of its business by way of acquisition, consolidation or merger. Notwithstanding the foregoing, this Agreement shall be binding upon the respective successors and assigns of either party hereto.

14.8 If any provisions of this Agreement are held invalid or unenforceable, unless the invalidity or unenforceability substantially frustrates the underlying intent and sense of the remainder of the Agreement, such invalidity and unenforceability shall not affect the validity or enforceability of any other provisions of the Agreement except those where the invalidated or unenforceable provisions comprise an integral part of, or are otherwise clearly inseparable from, the intent and sense of the Agreement. In the event any provision is held invalid or unenforceable, the parties will attempt to agree upon a valid and enforceable provision which shall be a reasonable substitute for such invalid or unenforceable provision in light of the intent of this Agreement and upon so agreeing, shall incorporate such substitute provision in this Agreement.

14.9 This document contains the entire Agreement between the parties pertaining to its subject matters and shall not be altered or modified, except in a writing signed by the party to be bound by such alteration or modification.

IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be executed by their duly authorized representatives as of the date and year first written above.

Boehringer Ingelheim Pharmaceuticals, Inc.

By:

J. Heyen, fast

Title: Sr. VP, Marketing

Date:

9/16/05

Boehringer Ingelheim Roxane, Inc.

By:

Robert C. Feeney

Title: President & COO

Date:

9/12/05